UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Biomedical Device Consultants & Laboratories of Colorado, LLC, Plaintiff, vs. TA Instruments - Waters LLC, Defendant.	Civil File No. 17-cv-03403 DWF/SER **PLAINTIFF'S REPLY IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION**

INTRODUCTION

In its opposition, Defendant TA Instruments – Waters LLC's ("TA") fails to rebut any of Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC's ("BDC") evidence concerning irreparable harm and fills the rest of the opposition with misdirection to hide from obvious flaws in its infringement or invalidity defenses. Once the Court understands the glaring holes and misdirection, it is clear that BDC has shown a likelihood of success and an injunction should enter. For instance, for the '224 Patent, TA offers *no* infringement defense and its invalidity defense relies entirely on an argument about Pickard that was *already considered and rejected* by the Patent Office.

First, TA offers no evidence to contradict the fundamental premises of BDC's irreparable harm arguments, leaving BDC's evidence largely undisputed. Instead, TA claims that the harms are "speculation" because they have not yet fully occurred. Yet, the entire purpose of a preliminary injunction is to prevent *threatened* harms from

occurring. TA further misdirects the Court by claiming BDC's alleged delay precludes preliminary injunctive relief. But, the authority upon which TA relies did not involve the parties negotiating potential resolution. In fact, the case law is clear that delay akin to that of BDC's is appropriate where negotiations are ongoing, especially given BDC's small size and the large expense of patent litigation.

Second, to refute BDC's clear likelihood of success, TA makes the extraordinary claim that BDC committed inequitable conduct, the "atomic bomb" of patent litigation. Yet, the statements identified by TA are all true, and TA never even cites the allegedly withheld references in its invalidity analysis or otherwise explains how they could be "but-for" material. TA does not come close to meeting its very high burden to prove inequitable conduct.

Third, TA offers no non-infringement defense to the '224 Patent. TA makes a very weak invalidity argument by attempting to argue that a patent that was thoroughly discussed by the Examiner (Pickard) is invalidating. As a last gasp, TA attempts to combine Pickard with the Woodward reference, which has nothing to do with heart valve testing and teaches away from incorporation of the element TA claims it provides.

Fourth, regarding the '935 Patent, TA misdirects the Court with arguments that clearly ignore the claim language and specification. In short, TA's protection of the motor of its product with a drip guard is similar to what is disclosed in the '935 Patent and in no way avoids infringement. Likewise, while an incompressible fluid cannot be "compressed," the fluid in TA's DuraPulse system is designed to be "under compression." With respect to invalidity, TA argues that the Swanson patent considered

by the Examiner anticipates the '935 Patent. However, Swanson operates on a principle that does not involve the use of an excess volume area or compliance chamber, which is presumably the same reason that the Examiner did not find it invalidating.

For these reasons, and the others discussed below, TA's opposition is meritless, and BDC's motion should be granted.

ARGUMENT

A. TA Has Not Refuted The Fact that BDC Will Suffer Irreparable Harm Without An Injunction

1. BDC's Evidence Is Admissible and Undisputedly Shows Irreparable Harm

Instead of refuting BDC's evidence of irreparable harm, TA argues it is hearsay. Ironically, TA acknowledges the well-established rule that the Court may consider hearsay evidence on a motion for preliminary injunction due to the hastened nature of such motions. Opp'n at 6 n.2; *see United HealthCare*, 2002 U.S. Dist. LEXIS 28262, at *18 (D. Minn. March 1, 2002) (citing *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *S.E.C. v. Cherif*, 933 F.2d 403, 412 n.8 (7th Cir. 1991); *Welker v. Cicerone*, 174 F. Supp. 2d 1055, 1059 N.2 (C.D. Cal. 2001)). None of the cases cited by TA are to the contrary—in those cases, the hearsay nature of the evidence went to weight, not admissibility.[1] *See Watkins Inc. v. Lewis*, 2002 U.S. Dist. LEXIS 19738, at *49 (D. Minn. Oct. 11, 2002) (holding that the hearsay evidence was too conclusory to support a finding of likelihood of success on the merits of a defamation claim); *U.S. Water Servs.*,

[1] One of the three cases, *A & L Labs., Inc. v. Bou-Matic, LLC*, 2003 U.S. Dist. LEXIS 12922 (D. Minn. July 21, 2003), does not concern hearsay at all but parol evidence. *See id.* at *10.

Inc. v. Watertech of Am., Inc., 2013 U.S. Dist. LEXIS 143024, at *9-10 (D. Minn. Oct. 3, 2013) (choosing to credit one declaration over another that had an additional layer of hearsay). Significantly, TA *never* disputes the evidence of BDC's irreparable harm with its own evidence.

For example, if TA has never discounted the price for its product below that of BDC for its VDT-3600i system, TA could have simply submitted a declaration saying so. Such a statement is conspicuously absent from the declaration submitted. Similarly, TA never disputes that BDC lost a customer to it. TA only claims that it "has no way of identifying the alleged 'customer.'" If TA needed to know the identity of the customer, it could simply have sought to conduct discovery. It chose not to do so, likely because in such an intimate market, it already knew the identity. TA also does not dispute that BDC has a reputation for innovation, that innovation is of particular importance in the industry, or that the market is subject to incumbency effects. Therefore, not only is BDC's evidence properly considered at this procedural stage, it is also largely undisputed.

Importantly, there is no requirement that BDC show that it has *already* suffered some form of irreparable harm. In fact, were BDC already harmed, TA would likely be arguing that the motion is moot. Rather, BDC must show that it there is a *threat* of irreparable harm. *Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Eng'rs*, 826 F.3d 1030, 1036 (8th Cir. 2016). The "alleged harm need not be occurring or be certain to occur before a court may grant relief." *Id.* at 1037. BDC has shown an actual threat of injury from each form of irreparable harm identified in its opening brief.

a. Lost Market Share

As explained in in BDC's opening brief, BDC is at risk of losing market share due to TA's infringement because BDC has a strong market position, the market is small with strong incumbency effects, and BDC has already begun losing sales to TA's infringing product. TA's response merely argues that BDC's evidence regarding its 80-90% market share relates to the global market rather than domestic market, of which BDC only has a 60% market share, Opp'n at 7, 9. Assuming *arguendo* that BDC has only a 60% share of the domestic market and only the domestic market is relevant,[2] 60% is still a dominant market position and BDC's point that it is the market leader is still valid. TA does not dispute that once a pilot program is complete, a customer will purchase many devices from a single supplier in order to reduce testing variables. As a result of this uncontested fact, incumbency effects exist, which means that lost market share is irreparable injury as explained at length in *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1336 (Fed. Cir. 2013).

b. Price Erosion

As explained in BDC's opening brief, BDC is experiencing pressure to lower its prices because TA has offered discounts that undercut BDC's price. TA never once denies offering these discounts. Instead, it merely argues that price erosion is not a form of irreparable harm. Federal Circuit precedent begs to differ. *Aria Diagnostics v.*

[2] The global market is the relevant market because TA's devices are made in the United States. Therefore, every sale throughout the world is of a device that infringes the Patents-in-Suit.

Sequenom, Inc., 726 F.3d 1296, 1304 (Fed. Cir. 2013); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1153-55 (Fed. Cir. 2011). TA's sole support for its position is dicta from an outlier case, *3M Co. v. Avery Dennison Corp.*, 2010 U.S. Dist. LEXIS 135140 (D. Minn. Dec. 21, 2010). In *3M*, the Court found no price erosion because the prices had already been cut prior to infringement and the plaintiff's expert also admitted that price erosion in the market was *reversible*. *Id.* at *29-30. Neither of those facts exists here, making *3M* inapplicable.

c. Lost Research and Development

As explained in BDC's opening brief, the market for medical device testing equipment is one in which innovation is particularly important. Once again, TA's response does not dispute this point. TA's sole response is to cite *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568 (Fed. Cir. 1996), which stands for the proposition that merely dedicating some revenue to research, without more, is not grounds for finding irreparable harm. *Id.* at 1578. Here, there is more—the market itself is one in which innovation is of extreme importance due to the innovation in the medical devices being tested. *See Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1456 (Fed. Cir. 1988) (affirming finding of irreparable harm where, *inter alia*, technology was new, was changing "fairly quickly," and substantial research was being done). Moreover, the revenue loss is not inconsequential, but rather significant because BDC's VDT-3600i is its best-selling product.

d. Injury to Reputation

TA argues that BDC has not shown "that it is in danger of" losing its reputation for innovation. BDC submitted evidence that it has a reputation for innovation, and that reputation is at least partly attributable to the (pre-infringement) uniqueness of its patented product VDT-3600i, which has become the industry standard heart valve testing system. It is disingenuous for TA to suggest that somehow BDC's industry standard product can compete against an infringing product without BDC being "in danger of" losing its market lure and reputation for innovation. *See Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344 (Fed. Cir. 2013).

2. Harm to BDC is Not Compensable by Money Damages, It is Irreparable

TA also argues that BDC's harms could be adequately compensated by money damages. This argument is directly at odds with TA's later argument that, if an injunction were to issue, its own "reputation and customer relationships" would be intangibly harmed. Opp'n at 41-42. If TA would be irreparably harmed by damage to its reputation and relationships with the market, so would BDC. TA's argument is also directly contrary to Federal Circuit precedent that has recognized that all of these types of harm are irreparable and cannot be remedied with money damages. *See* Opening Br. at 21 (collecting cases).

B. Any Delay in Bringing This Motion Does Not Refute the Irreparable Harm Shown

As anticipated by BDC in its opening brief, TA argues that a preliminary injunction should be denied because of BDC's alleged delay in bringing its motion.

Delay, however, is not a ground for denying an injunction where the parties are negotiating a potential settlement, where the infringer's activity does not become a "real threat" until later in time, or where the patentee is a small company that is taking a prudent approach before expending resources on litigation.

TA first argues that BDC delayed bringing this case since 2013. Opp'n at 12. But, the patents raised by BDC's motion for preliminary injunction did not even issue until November 2015 and January 2016. '224 Patent at [45]; '935 Patent at [45]. Further, the DuraPulse was not being sold in 2013 so there was no irreparable harm to be enjoined—all of the forms of irreparable harm discussed above depend on true competition between BDC's patented product and the infringing DuraPulse product. Indeed, TA chastises BDC for waiting for harm to develop, arguing that "[i]f BDC truly believed that the alleged infringement could cause irreparable harm, it would have sought a preliminary injunction when it realized the product was (allegedly) infringing its patents." Opp'n at 13-14. This, however, is precisely the point—the market presence of the DuraPulse, if any, was so minimal that BDC would not have been able to show any harm. Rather, BDC needed to wait until it actually could demonstrate irreparable harm. *See Brushnell Inc. v. Brunton Co.*, 673 F. Supp. 2d 1241, 1263-64 (D. Kan. 2009) (excusing twenty-three month delay where infringing product only recently became "real threat").

Moreover, the rationales behind why price erosion, loss of market share, and the like constitute irreparable harm hold true regardless of the alleged delay. They are grounds for an injunction "because it is so difficult to recover from such a loss." *Cordis*

Corp v. Medtronic Inc., 1986 U.S. Dist. LEXIS 17091, *9-10 (D. Minn. Dec. 1, 1986). The difficulty in quantifying the harm associated with price erosion, loss of goodwill, and loss of customers does not become less difficult as a result of any delay in this case. *Razer Auto, Inc. v. Omix-Ada, Inc.*, 2016 U.S. Dist. LEXIS 187596, *17 (C.D. Cal. Apr. 20, 2016) (finding price erosion, loss of goodwill, and loss of customers constitute irreparable harm because they are "difficult to quantify"). Simply, the delay does not suggest less irreparable harm here.

TA also attempts to misdirect the Court by citing two cases for the proposition that "negotiating with the alleged infringer is not an excuse." Opp'n at 14. These cases do not reject negotiation as a justification, but instead concern the *lack* of negotiation. See *Novozymes A/S v. Danisco A/S*, 2010 U.S. Dist. LEXIS 101962, at *11 (W.D. Wis. Sept. 24, 2010) (noting that there was no negotiation, the plaintiff merely asked for accused product to be withdrawn from market); *Yamashita v. Wilbur-Ellis Co.*, 2006 U.S. Dist. LEXIS 33044, at *20 (N.D. Cal. May 11, 2006) (noting there was no negotiation, the patentee had merely sent repeated demands to cease and desist). In contrast here, BDC attempted in good faith to resolve the case through actual negotiation. Weinberg Decl. ¶ 20.

C. BDC Is Likely to Prevail on the Merits

1. BDC Did Not Commit Inequitable Conduct

Remarkably, TA argues that a substantial question exists regarding inequitable conduct. Inequitable conduct is extremely rare; it is the "atomic bomb" of patent litigation. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir.

2011). As the "atomic bomb," inequitable conduct has a notoriously high standard, it requires both "but-for" materiality and that an intent to deceive the Patent Office be the *single most reasonable inference* from the evidence. *Id.* at 1290, 1291. TA cannot meet these demanding standards.

TA argues that BDC's CEO falsely "suggested that 'excess volume area' is a term of art based on ISO 5840" when that term is not actually defined in ISO 5840. Opp'n at 17. BDC's CEO never made any such suggestion—the citation relied on by TA is to a page in which BDC's patent attorney stated: "the concept of using a compliance chamber to store excess volume of a test fluid in a *real-time, physiologically accurate,* cardiac valve test system is well known *for the purpose of substituting for the arteries* of the human circulatory system (in fact, compliance is required by ISO 5840 in Annex L and detailed guidelines for compliant chambers are provided in Annex F)." This is a true statement. The only person that ever stated that excess volume area is a term of art was the *Examiner*. *BDC itself* made no such statement, and TA cannot show that the single most reasonable inference is that BDC intended to deceive the Patent Office.

The second instance of alleged inequitable conduct is that BDC distinguished accelerated durability testing from real-time testing by noting that real-time testing "should be conducted in a pulse duplicator that produces pressures and flow waveforms that approximate physiological conditions." Billiar Decl. Ex. 3 at 17. TA argues this was misleading because it is inconsistent with the requirement of durability testing that test valves "experience the *full range of occluder motion* associated with normotensive conditions (see Table 1)." There is no inconsistency: that valve leaflets ("occluders")

must experience a full range of motion (i.e., open and shut) is simply irrelevant to BDC's statement that durability testing does not require pressures and flow waveforms that approximate physiological conditions. Again, given the truthfulness of BDC's statements, there can be no inequitable conduct.

The third instance of alleged inequitable conduct is that BDC stated that the use of a compliance chamber in an accelerated durability testing system was "entirely new." TA claims this statement was false because Annex F of ISO 5840 "expressly" provides the use of a compliance chamber. But, the "compliant chamber" referenced in Annex F references an entirely different concept from the compliance chamber in the Patents-in-Suit. As set forth in its title, Annex F applies to "in vitro testing of ***unstented*** or similar valves," and requires them to be tested in "compliant chambers" if "the pressure difference and/or regurgitation is a function of the ***compliance of the vessel or chamber into which the valve is to be implanted***." Billiar Decl. Ex. 7 at 24 (emphasis added). Such unstented valves are sewn directly to tissue. If a valve is to be directly sewn to tissue that is "compliant," i.e., not rigid (e.g., the aorta or heart muscle), then the unstented valves should be tested using mounts or holders that are also "compliant," i.e., non-rigid. Suppl. Girard Decl. ¶ 14. This is a fundamentally different type of "compliance chamber" than referenced in the patents. It is a sample holder; it is not an excess volume area that provides *system compliance* like that referenced in BDC's statement to the Examiner. *Id.* ¶¶ 15-16. Therefore, TA has failed to show but-for materiality of the statement or that intent to deceive is the single most reasonable inference.

Finally, TA claims that several other systems had compliance chambers and that BDC "should have been aware" of these systems. There is no evidence BDC knew of these references, and as a matter of law, "should have known" is insufficient to meet the demanding *Therasense* intent standard. 649 F.3d at 1290. Moreover, the lack of materiality of these references is betrayed by the fact that none of them form the basis for any of TA's anticipation or obviousness arguments.

TA fails to raise any question, much less a substantial question, regarding inequitable conduct.

2. BDC Is Not Required to Construe Every Claim Term

TA argues that BDC's motion should fail without further consideration as it did not propose constructions for five claim terms. Opp'n at 20. The law imposes no such requirement—claim construction is only required where term meaning is in dispute or when needed to clarify whether a term covers an element of the prior art or accused device. *02 Micro Int'l v. Beyond Innovation Tech.*, 521 F.3d 135, 1362 (Fed. Cir. 2008). Furthermore, no claim construction is needed where a claim term is readily understood. *3M Innovative Props. Co. v. EnvisionWare, Inc.*, 2010 U.S. Dist. LEXIS 128664, at *6 (D. Minn. Dec. 6, 2010). TA offers no proposed construction of its own for the five terms, and none form the basis of its defenses.[3] TA's claim construction argument is simply irrelevant.

[3] For this reason *Fair Isaac* is distinguishable. In that case, the defendants both offered constructions of the disputed terms and explained their relevance to the merits. Here, the only term that may need construction is "under compression" because TA uses two different meanings in its validity and infringement arguments. BDC continues to

3. ’224 Patent

a. Infringement

TA does not dispute BDC’s infringement argument and thus the Court should find a likelihood of success that TA infringes the ’224 patent.

b. Validity

i. Written Description

TA argues there is no written description support for the limitation in claim 1 of the ’224 Patent that the rate of the system be “greater than 200 bpm.” The test for sufficient written description “is whether the disclosure of the application relied upon *reasonably conveys* to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date” of the application. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (emphasis added). The application for the ’224 patent meets this standard because it repeatedly references “accelerated” testing as well as “fatigue” testing, which the person of ordinary skill would recognize as referring to accelerated testing. Suppl. Girard Decl. ¶ 17; Tahdooahnippah Suppl. Decl. Ex. A. The ISO standards for real-time testing require testing at three speeds: 45 bpm, 70 bpm, and 120 bpm. Tahdooahnippah Suppl. Decl. Ex. B, Annex L, L.4.3.3. Even the standards for “quasi-real time durability testing” (an intermediate step between real-time and accelerated testing) requires rates only up to 200 bpm. *Id.* Ex. B, § 3.44. The ISO

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believe that the plain and ordinary meaning governs. As explained below, for purposes of this motion, that plain and ordinary meaning is “under pressure” as conceded by TA in its validity argument.

also recognizes that "expected" physiological conditions are less than 200 bpm. *Id.* Ex. B, § 6, Table 1. Therefore, by referencing "accelerated" or "fatigue" testing, the application "reasonably conveys" that BDC was in possession of a device that operates at rates greater than 200 bpm.

TA's entire written description argument boils down to the mere fact that the application did not specifically recite 200 bpm even though the application was clearly limited to accelerated testing. Simply because the Examiner sought to clarify this point does not mean that the written description is insufficient. The law is clear that *in haec verba* recitation is not required to meet the written description requirement. *Ariad*, 598 F.3d at 1352.

ii. Anticipation/Obviousness

TA argues that Pickard anticipates or renders obvious (when combined with Woodward) claims 1 and 6 of the '224 Patent. "A claim is anticipated only if each and every limitation is found either expressly or inherently in a single prior art reference." *Ericsson v. D-Link Sys.*, 773 F.3d 1201, 1224 (Fed. Cir. 2014). "[A]nticipation must be proven by clear and convincing evidence." *Id.* TA's anticipation argument is meritless. The Examiner already specifically found that Pickard did not disclose an accelerated system and, therefore, each and every element of the claim was not in the reference. TA's only counterargument is that BDC did not show that Pickard was incapable of being operated above 200 bpm. This argument ignores that it is TA's burden to show that Pickard taught operation above 200 bpm. TA offers no evidence to meet this burden, much less the weighty evidence that TA would need to prove by clear and convincing

evidence that the Examiner made a mistake in finding that Pickard did not disclose the limitation. *See Sciele Pharma, Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012) (noting that as a practical matter burden is weightier where reference was already before the Patent Office).

TA further argues that it would have been obvious to operate the Pickard device at more than 200 bpm because Woodward teaches that young adults can have heart rates above 200 bpm during short exhaustive exercise. "Even when all claim limitations are found in prior art references, the fact-finder must determine what the prior art teaches, whether prior art teaches away from the claim invention, and whether there was motivation to combine teachings from separate references." *Cheese Sys. v. Tetra Pak Cheese & Powder Sys.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013). The claims are not obvious because one skilled in the art would never have been motivated to combine Pickard and Woodward in light of their teachings away from the '224 Patent. Moreover, one skilled in the art would not understand Pickard, as a patent related to real-time valve testing, would apply to testing above 200 bpm outside of the ISO 5840.

Pickard is a real-time heart valve testing system that teaches that compliance chambers can be used to simulate the compliance of the veins and arteries in the human body. Pickard col.3, ll.46-55. Since Pickard is in the field of real-time testing, one of skill in the art would look to that field to the normal rate range for testing. The ISO 5840 standard for real times testing suggests the normal testing ranges: 45 bpm to 120 bpm. Moreover, the top end of the physiological range set forth in Table 1 is 200 bpm. One would not look to Woodward to understand testing ranges for valves because Woodward

relates to an artificial heart (which pumps blood while a patient's heart is emptied or stopped due to surgery). Woodward col.1, ll.13-23.

Even if one were to look at Woodward to understand testing rates, Woodward teaches away from building a device operating above 200 bpm. While Woodward notes that hearts of children can beat faster than 200 bpm, it does *not* teach building any device capable of operating faster than 200 bpm. Instead it teaches that "only resting conditions are of concern" and therefore its device should operate in a range of 30 bpm—125 bpm with an "upper limit" around 190 bpm. Woodward col.1, ll.64-5, col.17, ll.25-26. By contrast, in looking to understand the ranges at which Pickard would operate, one would look at the ISO 5840. There is no substantial question of invalidity for the '224 Patent.

4. '935 Patent

a. Infringement

TA argues that the DuraPulse lacks two limitations from claim 1 of the '935 Patent (which was the only independent claim raised by BDC's motion): (1) having a pressure source in fluid communication with the fluid distribution chamber; and (2) having a test system fluid under compression. But, TA arguments ignore the plain language of the specification to create non-infringement positions that do not exist.

i. Fluid Communication Between Pressure Source and Fluid Distribution Chamber

TA argues that because the DuraPulse's motor, which was defined by BDC's infringement expert as part of the pressure source, has a "drip guard" to protect the motor from damage by the fluid, the pressure source is not in fluid communication with the

system. Obviously, the drip guard is part of the pressure source. Any pressure source that includes a motor needs some barrier to prevent fluid from entering the inside of the motor. The ’935 Patent expressly discloses such a barrier, which it is describes as a “diaphragm 215.” ’935 Patent col.13, ll.10-27. Simply because there is a barrier protecting the motor from the fluid does not prevent the pressure source from being in fluid communication with the fluid distribution chamber. The barrier is part of the motor assembly that makes up the pressure source, which is in fluid communication with the fluid distribution chambers. Suppl. Girard Decl. ¶¶ 6-8.

ii. “Under Compression”

TA argues that its test system fluid is an incompressible liquid and therefore cannot be “compressed.” The claim language, however, does not require that the fluid be “compressed,” it requires that the fluid be “under compression.” Incompressible liquids can be placed “under compression.” In other words, compressive forces can be placed on liquids causing them to be placed “under pressure.” Suppl. Girard Decl. ¶ 11. In her invalidity analysis of the ’935 Patent, TA’s expert concedes that she understands “under compression” to mean “under pressure.” Billiar Decl. ¶ 76. TA does not dispute that the excess volume area in the DuraPulse stores test fluid when the fluid is under pressure, as explained in BDC’s expert declaration. Girard Decl. at 13-14. Therefore, the DuraPulse’s test fluid is placed “under compression” and infringes.

b. Validity

TA argues that Swanson anticipates claims 1 and 9 of the '935 Patent. This is an extraordinary proposition given that, like Pickard, Swanson was disclosed to the Patent Office. '935 Patent at [56]. The Examiner did not consider Swanson material to patentability. This is with good reason: Swanson discloses neither a compliance chamber nor an excess volume area as required by the claims.

The area identified by TA as a compliance chamber and excess volume area is the interior of a bellows, but only part of the time when the bellows is pulled by a lever to expand. The Swanson device actually has several bellows, which expand or contract based on whether the swash plate is higher or lower on one side of a fulcrum. This movement cycles fluid through the system: the bellows that expand suck test system fluid through the open valve into them, while the bellows that contract (i.e., move upwards) push fluid through the valve.

These bellows operate fundamentally differently than a compliance chamber. As noted in BDC's opening brief, a compliance chamber must *absorb* pressure from the system.[4] TA never explains how the bellows act to absorb pressure and, contrary to its conclusory assertion that they do, they do not. Absorption is a passive act—it connotes an element that passively takes in something, such as energy or pressure, from the

[4] Although TA does not identify "compliance chamber" as term in need of construction, Opp'n at 20, or ever formally offer a construction of "compliance chamber," TA criticizes BDC's proposed construction of the term, *id.* at 22. However, even if the Court were to adopt the construction that TA seems to suggest, that construction still requires that pressure be absorbed. *Id.* Therefore, to the extent there is a dispute regarding the proper construction, it is not material to this motion.

outside. The bellows are not passive elements, they are active elements. When the bellows expands, it sucks in fluid but does not store pressure like a compliance chamber does. Suppl. Girard Decl. ¶ 22. The evidence of a compliance chamber's storage of pressure is that the chamber returns that pressure to the system which closes the valve (working similar to a spring). *Id.* ¶ 21. Because the bellows does not store pressure, it cannot return pressure to the system but instead must create *new* pressure to close the valve. *Id.* ¶ 22. Swanson creates this new pressure mechanically when the motor turns a swash plate that compresses the bellows and reverses the system (operating like a see-saw). *Id.*

Moreover, the bellows in Swanson are also not an excess volume area. The concept of an excess volume area is that there is a volume for test system fluid to occupy in response to the fluid being under compression that is in "excess" of the volume area occupied when not under compression. Suppl. Girard Decl. ¶ 24. In the Swanson system, there is no "excess" to its volume area reactive to the fluid being under compression. *Id.* Rather, the volume receiving the fluid is the same as the volume sending the fluid; the fluid conduits, chambers, and bellows are identical on each side. *Id.*

D. Balance of Harms Favors Injunction

While arguing that BDC suffers no irreparable harm from losing market share to TA, TA also argues that the balance favors it because it will be irreparably harmed if it cannot participate in the market. TA cannot have it both ways. In reality, losing market

share is harm, but the balance of the harms favors BDC because TA's sales are small compared to BDC's, which has a dominant market position as even TA acknowledges.

E. Public Interest Favors an Injunction

TA argues that the public has an interest in receiving medical devices (here, prosthetic heart valves). However, TA does not make medical devices, it makes medical device testing equipment, and therefore TA's cases regarding injunctions against medical device manufacturers are inapposite. Even if TA is enjoined, medical devices will still be available to the public, as they can be tested with BDC's testing equipment (or other non-infringing testing equipment). This factor favors an injunction.

F. TA Provides No Support for Its High Bond

The purpose of a bond is to approximate damages for a wrongful injunction. Fed. R. Civ. P. 65(c). TA does not dispute that its total sales during the life of the product are under $500,000. Thus, the potential sales during the pendency of this case will be a fraction of that; and there is no evidence that any of the sales have generated profits. As a result, the bond should be very low – on the order of $10,000.

CONCLUSION

For the reasons stated herein, BDC respectfully requests that this Court grant BDC's motion for preliminary injunction.

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